

Notice of Allowability**Application No.**

09/648,081

Examiner

Frank W Lu

Applicant(s)

WANG ET AL.

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/29/2003.
2. ☒ The allowed claim(s) is/are 122-125 and 127-154.
3. ☒ The drawings filed on 29 April 2003 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☒ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No. _____.
- (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
- (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- 1 ☐ Notice of References Cited (PTO-892)
- 3 ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 5 ☐ Information Disclosure Statements (PTO-1449), Paper No. _____
- 7 ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 2 ☐ Notice of Informal Patent Application (PTO-152)
- 4 ☒ Interview Summary (PTO-413), Paper No. 8/03
- 6 ☒ Examiner's Amendment/Comment.
- 8 ☒ Examiner's Statement of Reasons for Allowance
- 9 ☐ Other

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REASONS FOR ALLOWANCE

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. David Preston (Reg. No. 38, 710) on August 21, 2003.

2. The application has been amended as follows:

Delete claim 126. Replace "claim 144" in claim 144 with "claim 143".

122. (Amended) A method of detecting a mutation or single nucleotide polymorphism (SNP), comprising:

- a) contacting one or more probes that comprise DNA with a survey population of RNA molecules under conditions that promote hybridization between complementary nucleic acid molecules to generate a probe-survey population mixture of nucleic acid molecules that comprises at least one of said one or more probes hybridized to one or more survey population RNA molecules, wherein [:]said one or more probes are at least partially complementary to one or more RNA molecules known to be or suspected of being present in the survey population, further wherein terminal nucleotide of said one or more probes [terminate in known or suspected] is a SNP[S] or mutation[s];
- b) treating said probe-survey population mixture of nucleic acid molecules with at least one nuclease that digests single-stranded DNA molecules, such that non-base-paired deoxynucleotides

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are digested, to generate a population of nucleic acid molecules comprising one or more nuclease-protected probes;

c) contacting said population of nucleic acid molecules comprising one or more nuclease-protected probes with a solid support that comprises one or more attached nucleic acid molecules under conditions that promote hybridization between complementary nucleic acid molecules, wherein said one or more attached nucleic acid molecules are at least partially complementary to said one or more probes, to generate one or more attached nucleic acid molecule/nuclease-protected probe complexes; and

d) detecting at least one of said one or more attached nucleic acid molecule/probe complexes to detect [a mutation or SNP] said SNP or mutation.

123. (Amended) The method of claim 122, wherein the terminal nucleotide [at the site of said known or suspected mutation or SNP] is labeled.

129. (Amended) The method of claim 122, wherein said [one or more] probes [is] are two or more probe.

139. (Amended) The method of claim 135, wherein said [one or more] attached nucleic acid molecules are two or more attached nucleic acid molecules.

142. (Amended) The method of claim 140, wherein said [one or more] probes [is] are more than one probe.

150. (Amended) The method of claim 147, wherein said [one or more] attached nucleic acid molecules [is] are two or more attached nucleic acid molecules.

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151. (Amended) The method of claim 140, in which said at least one polymerase is one selected from [of]the group [comprising] consisting of T4 DNA polymerase, T. aquaticus polymerase, Klenow fragment, T7 RNA polymerase, DNA polymerase 1, and SP6 RNA polymerase.

3. The following is an examiner's statement of reasons for allowance:

Claims 122-125 and 127-154 are allowable in view of applicant's amendment filed on April 29, 2003 and the examiner's amendment. The closest prior art in the record are Kris *et al.*, (US Patent No., 6,238,869, filed on June 21, 1999), Felder *et al.*, (US Patent No. 6,232,066, filed on July 2, 1998), Zhao (US Patent No.6,448, 010, priority date: October 6, 1999), Shah *et al.*, (US Patent No.5, 629,156, filed on December 29, 1994), and Nielson *et al.*, (US Patent No. 5,773,257, published on Jun 30, 1998). These prior art do not teach to detect a mutation or SNP which is a terminal nucleotide of said one or more probes in step d) of claim 122 and step c) of claim 140. These prior art either alone or in combination with the other art in the record does not teach or reasonably suggest a method of detecting a mutation or single nucleotide polymorphism and a method of detecting at least one RNA molecule in a survey population of RNA molecules which comprise all of the limitations recited in claims 122 and 140. Note that, according to the definition of "uniform" in the dictionary, uniform number of bases in step c) of claim 140 is considered as the same number of bases.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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4. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu
August 25, 2003


ETHAN WHISENANT
PRIMARY EXAMINER